McKesson Operations Manual
for Pharma Distribution

MOM Main Index

Controlled Substance Monitoring Program

General Description	Overview of Detailed Steps	Detailed Steps	Attachments	Related Information
Author / Owner	Revision History	Search DistOps	Contact Us	

General Description

Task: **ATTENTION SOP REQUIRED ACTION: VAWD NOTIFICATION REQUIRED FOR ANY UPDATES.**
Send notice of any updates to Director of Regulatory Affairs and Director of Distribution & Quality..
Any Updates to this SOP must be forwarded along to the (National Association Board of Pharmacy)

This procedure outlines requirements and activities to proactively monitor customer's orders and purchases of DEA controlled substances and actions to take based upon analysis of customer orders and purchases..

Purpose: The purpose of this process is to:

- Proactively review the customer's orders and purchases for all controlled substances in order to detect and prevent diversion.
- Set and maintain customer's thresholds for all controlled substances
- Make informed decisions based upon established threshold information
- Build a documented business case to substantiate the volume of controlled substances purchased by McKesson customers.
- Report to the DEA those orders / purchases / customers designated as "suspicious".

The DEA expects McKesson to *"know their customer"*. This means understanding the customer's business, *why* they purchase as well as how much they purchase. Factors such as type of business, internet activities, type and quantity of products purchased should be considered when evaluating a customer.

While this program encompasses all of McKesson Pharma Operations, there are certain actions that are the responsibility of Retail National Account (RNA) partners on behalf of operations. These actions are noted in the steps below.

Reports

There are multiple reports developed to allow McKesson to monitor customer orders and purchases of controlled substances by the net number of dosage units sold based on the DEA's Controlled Substance Generic Base Code ID. McKesson will investigate customer activity when an order of a given generic base ingredient exceeds a predefined dosage unit threshold within a calendar month.

Additions or deletions of items will be managed through the Regulatory Department by submitting a problem request to Business Intelligence- Functional (BI-FUNC).

For the purpose of these reports, all sales to a DEA license number are being accumulated, therefore sales to multiple account numbers with the same DEA license number are consolidated. Sales are added together regardless of fill dc.

When to Daily

PLAINTIFFS TRIAL EXHIBIT
P-12627_00001

do: As needed

Target Audience Sign Off **Target Audience Signoff Form.doc**

Top

Overview of Detailed Steps

Top

Detailed Steps

1. Thresholds

1.1 Initial Program Thresholds

Analysis was conducted on every McKesson customer. Thresholds with an additional margin were established based upon a review of customers' purchases over a twelve month period.
DEA has assigned each controlled substance to a "base code" or also referred to as the "Administration Controlled Substance Code Number".
The controlled substance thresholds were established using the DEA base code.

1.1.1 Regulatory Threshold Limits

The Regulatory Directors determined "Regulatory Limits" for every base code. The regulatory limits are conservative beginning dosage amounts that allow a pharmacy to order controlled substances until such time that individual thresholds can be set.

1.1.2 Family Threshold Limits

All McKesson customers were evaluated and classified into like business segments based upon type of business and monthly dollar RX sales. Additionally, Six Sigma analysis helped to identify appropriate threshold amounts for every controlled substance and for every family type. Out of that information, a matrix of family codes and threshold amounts were developed. (See attachments)

NOTE: If a customer has never purchased a particular "base code" before, Immediately upon their first purchase, the family threshold limit for that base code will be applied.

1.2 Establishing "New Customer" Thresholds

As McKesson accepts new customers, consideration needs to be given to establishing thresholds for controlled substances. Decisions will be made on a case by case basis using the guidelines listed below.

1.2.1 Retail National Account (RNA), MHS, Government Customers

Correspondence will be between McKesson sales and the customers corporate headquarters. Sales will obtain the necessary information so McKesson's regulatory department can establish appropriate thresholds.

How to do:

Upon contract signing of new account(s), customer will provide to McKesson national accounts a completed customer questionnaire (see on-boarding process in step 3 below). In addition, customer will provide at least 3 months sales history (at store level) consisting of:

- NDC number
- Item description with unit of measure
- Purchase quantity (either saleable units or dispensing units)
- Months purchased

Result:

Once the above data has been obtained it should be disseminated as follows:

- Original completed / approved questionnaire to be retained with RNA director of business process as indicated in step 5 below.
- Copy of completed questionnaire to be sent to appropriate Director of Regulatory Affairs for review and approval.
- Sales history data to be sent to Supply Chain Services/Inventory Analytics in Carrollton

A. Regulatory Affairs
   1. Directors will review the questionnaire for completeness and either approve or reject. Rejected forms to be corrected and resubmitted.
   2. Directors will review completed questionnaire and based upon the information contained, assign the appropriate "family code" to each customer account.
   3. Directors will either;
      a. forward Excel spreadsheet listing family code assignment and account information to masterdata2@mckesson.com as approval to load family code to master data. To be loaded within 24 hours of receipt days of initial receipt
      b. input family and account data into Vistex as approval. To be loaded within 24 hours of input.
   4. Once receipt of loading has been received, DRA will notify Sales Rep, SA and DC
   5. Directors will forward copy of approved questionnaire to DC's for their files.

B. Carrollton Analysis
   1. Purchase history data will be analyzed and imported into a "CSMP Purchase History Spreadsheet" and forwarded to DRA.
   2. DRA analyzes the data, determines threshold amounts and uploads data to CSMP/SAP site

3. DRA's will receive immediate indication of successful upload
4. DRA will notify national accounts upon completion of threshold upload.

Special warnings:

NOTE: The customer and customer #'s need to be active in the system prior to loading DEA family.
If no purchase history is provided, the customers' thresholds will remain at the associated family designation.

If an error occurs:

If the Vistex system is not available and/or the Director of Regulatory Affairs does not have access, the approval process for DEA Family uploading can be maintained via an email attachment whereby the Director gives approval.

1.2.1.1 Existing Customer / New Location

As the customer relationship is pre-existing, national accounts and regulatory have previously reviewed the customers' controlled substance requirements. Correspondence will be between McKesson National Accounts and the customer's corporate headquarters. National Accounts will obtain the necessary information so McKesson's regulatory department can establish appropriate thresholds.

How to do:

A. National accounts will notify the appropriate regulatory directors via email of an anticipated new location opening.
B. Email to contain, Store name, Location, chain ID, DEA # and date of anticipated store opening
C. DRA will ascertain the default family code based upon previous analysis of customers existing locations and reply via email with family code and their approval to load into master data within 2 business days.
D. As the new location has no previous sales history, the default family and associated thresholds will be utilized until such time the locations purchases warrant threshold review.
E. DRA will respond to national accounts upon completion of threshold assignment.

Special warnings:

Note: The customer #'s need to be active in the system prior loading/assigning DEA family.

If an error occurs:

If the Vistex system is not available and/or the Director of Regulatory Affairs does not have access, the approval process for DEA Family uploading can be maintained via an email attachment whereby the Director gives approval.

1.2.2 All Other Account Types (independent, mail order, etc)

Correspondence will be between McKesson sales and the customers corporate headquarters/home office and/or owner. Sales will obtain the necessary information so

McKesson's regulatory department can establish appropriate thresholds.

How to do:

Upon contract signing of new account(s), customer will provide to McKesson sales representative a completed customer questionnaire (see on-boarding process in step 3 below). In addition, customer will provide at least 3 months sales history consisting of:

- NDC number
- Item description with unit of measure
- Purchase quantity (either saleable units or dispensing units)
- Months purchased

Result:

Once the above data has been obtained it should be disseminated as follows:

- Original completed questionnaire to be retained at the DC in the CSMP file as described in the document retention section 5 below.
- Copy of completed questionnaire to be sent to appropriate Director of Regulatory Affairs
- Sales history data to be sent to Supply Chain Services/Inventory Analytics in Carrollton

A. Regulatory Affairs
   1. Directors will review completed questionnaire and based upon the information contained, assign the appropriate "family code" to each customer account.
   2. Directors will either;
      a. forward Excel spreadsheet listing family code assignment and account information to masterdata2@mckesson.com as approval to load family code to master data. To be loaded within 24 hours of receipt days of initial receipt
      b. input family and account data into Vistex as approval. To be loaded within 24 hours of input.
   3. Once receipt of loading has been received, DRA will notify Sales Rep, SA and DC

B. Carrollton Analysis
   1. Purchase history data will be analyzed and imported into a "CSMP Purchase History Spreadsheet" and forwarded to DRA.
   2. DRA analyzes the data, determines threshold amounts and uploads data to CSMP/SAP site
   3. DRA's will receive immediate indication of successful upload
   4. DRA will notify national accounts upon completion of threshold upload.

Special warnings:

Note: Customer and customer #'s need to be active in the system prior to loading/assigning DEA family.

If an error occurs:

If the Vistex system is not available and/or the Director of Regulatory Affairs does not have access, the approval process for DEA Family uploading can be maintained via an email attachment whereby the Director gives approval.

1.3 Threshold Change Requests

Existing customers may request a re-evaluation or increase to their existing controlled substances threshold due to business requirements and/or and emergency situation. All requests for a threshold change must be documented on the "Threshold Change Request" form located at the Regulatory SharePoint website **http://collaborate.mckesson.com/SiteDirectory/WMS/RegAffairs/default.aspx** as directed

below.

NOTE: All requests for normal threshold changes need to be completed by a McKesson account manager and /or McKesson DC management. Emergency threshold requests may be initiated through the DC management.

1.3.1 Ordinary Threshold Change Request

The decision process time frame will vary depending on the nature of the request, availability of documentation and previous due diligence.

How to do:

All threshold change requests must be submitted via the Regulatory Affairs SharePoint website (**http://collaborate.mckesson.com/SiteDirectory/WMS/RegAffairs/default.aspx**), reviewed and approved by the Operations Management Team of the Distribution Center servicing the account, and the customer's associated home office or regulatory department. Threshold change requests (TCRs) should be the Director of Regulatory Affairs responsible for the Region. A template for recording these requests electronically has been created. The directions are listed below. NOTE: Level I investigations and TCRs can be performed using the same template. The steps below detail the all areas of the form. The requests can be made by anyone authorized by the DO/DCM to do so. RNA managers are likewise authorized through RNA management.

A. Access the SharePoint Regulatory Affairs website and, from 'Lists' in the left margin, select Add Customer TCR and Other Documents Here'.
B. From the header, select 'New'.
C. Complete all required fields identified by the red asterisk next to the heading.
    1. Name the document. Generally this is accomplished by listing the customer name and document type. For example, Mahoney's Pharmacy TCR. Note: 'Title' does not refer to the official title of the submitter. It refers to the document and will be used as a reference tool for research.
    2. Enter your name in the 'Submitter Name' filed.
    3. From the drop down menu, select the servicing distribution center. RNA account managers will select the specific Retail National Account.
    4. Enter the customer name.
    5. Customer contact, title and phone number are optional.
    6. Enter the customers DEA number.
    7. Enter the Customer's account number.
    8. From the drop down menu, select the document type (TCR in this case).
    9. Enter the supporting information relative to the change being requested. Be specific with your language.
D. Although the following information fields are not identified with an asterisk, they are required for TCRs.
    1. From the drop down menu, select TCR type (permanent or temporary).
    2. From the drop down menu, select the reason for the TCR.
    3. From the drop down menu, select the base ingredient.
    4. From the drop down menu, select the action.
    5. From the drop down menu, select the amount.
    6. When complete, select 'OK' at the bottom of the template.
E. The template can be used for multiple basecode changes.
F. RNA accounts where customers are completing the old style forms will post documents as follows:
    1. Follow all steps listed in number 2 above.
    2. From the header on the template form, select attach file
    3. Attach the old form TCR from the customer.
    4. When complete, select 'OK' at the bottom of the template.
G. Correctly executed TCRs will generate automatic email notifications to the submitter and the approver.
    1. Approves will view the document through the link to make sure they are complete and accurate.
    2. They will then approve the document by selecting 'Edit' within the email body.
        a. The fast path will take the approver to the Regulatory SharePoint approval screen.
        b. Select 'Edit' from the header.

c. Select either 'approved' or 'denied' from the drop down menu.
d. Comments are optional
e. Select 'Complete' at the bottom of the template.

H. A validation email is automatically generated by SharePoint to the submitter and the approvers informing all that the document is complete and approved.
I. SharePoint automatically files the document in the "Historical TCR and Customer Documents" page accessible from the 'Lists' menu on the Regulatory SharePoint site.

Refer all questions to your Regional Director of Regulatory Affairs.

1.3.2 Emergency Threshold Change Request.

The decision process time for an emergency request shall be 2 hours from the point of customer contact

How to do:

A. The decision of whether a request is truly an emergency lies with the DC management.
   1. Once DC management has determined that a request is an emergency, the DC management will collect all the pertinent information regarding the request on the Threshold Change Request form located at the SharePoint Regulatory site. If the DC management approves the request, they will contact their DRA (24/7) via the contact call chain described here: (phone numbers previously communicated)
      a. Contact your region's DRA (office/cell/home). If not available
      b. Contact Gary Hilliard (office/cell/home). If not available
      c. Contact any other DRA (office/cell/home)
   2. If the DRA concurs with the DC management's assessment, they will update the customers' thresholds immediately.
   3. DC management will notify the customer immediately upon approval of the threshold change.
   4. If DC management and/or DRA rejects request, customer is to be notified immediately by DC management of denial.
   5. All results (denial or acceptance) are to be documented on threshold change form and retained by DC management(with copy to DRA) in CSMP file.

1.3.3 DRA Required Standard Text

This step is a requirement for Directors of Regulatory Affairs only

When making any change to a customers threshold (temporary and/or permanent) you will need to enter text in the text field before a threshold will be accepted.

At a minimum, you will indicate the following in the text field:
date of TCR, current threshold amount, new threshold amount, initials of person making change. (if change is a temporary, indicate that in text as well).

Section Top

2. Threshold Review

Regulatory department will review/assess customer thresholds during the month. Additionally, customers that approach a predetermined % of threshold maximum or exceed maximums will receive messaging as shown below.

- Threshold Warning: Invoice & Delivery Doc only
  - **Approaching Monthly Regulatory Purchase Limit**
- Omit Code V: Threshold Limit
  - Short Message on some Front End Systems: **Monthly Max Exceeded**
  - Long Invoice Message: **Monthly Regulatory Maximum Purchases Exceeded**

NOTE: See example of invoice in attachments!

2.1 Threshold Warning

When a customer that has reached the threshold warning has been detected, The DRA will notify DC management and sales. Sales and/or DC management may contact the customer to discuss threshold levels at their discretion. If a threshold change is requested, follow the change request process in step 1.3 above. Any communication with customers must be documented (using general communication form in attachments and/or SharePoint) and retained in the CSMP file.

2.2 Threshold Excursion

Once a customer has reached their monthly maximum threshold amount, all subsequent orders for that item will be blocked. This triggers the level review process as detailed in Level review steps below.

The only way an item can be "unblocked" is if
· Threshold is temporarily changed
· Threshold is permanently changed
· Customer returns product and they fall below threshold
· Sales history is "refreshed" at the beginning of a new month, meaning sales are set back to zero and customer is once again allowed purchase up to threshold amounts.

Special warnings:

Note: All lines that breach the threshold will be cancelled in their entirety. No partial quantities will be filled under the threshold for those lines.

2.2.1 Level 1 Review - RNA Customer

The RNA support team will be responsible for initiating/compiling the level 1 review for RNA customers.

How to do:

Once the RNA support team has been informed of the threshold incursion, they will

- notify and request information from one of the following: the customers regulatory department, corporate office, regional management team or McKesson liaison regarding the item(s) in question.
- solicit feedback from the RNA customer and document information on the combination RNA threshold change/level 1 form in the attachments section. RNA support team will include all pertinent information as directed in the form; as well as the name, title, phone of person contacted/providing information.
- generate Level 1 documentation in SharePoint for appropriate Director of Regulatory Affairs review
- initiate a threshold change requests in SharePoint if needed (see section 1.3 above)

Result:

It is imperative to document the following information regarding your Level 1 discussion with the customer:

- name of person called
- reasoning for attempted threshold incursion
- has customer taken on any new business recently? if so explain.

- all additional information discussed pertaining to level 1.

Failure to complete this area will result in rejection of Level 1 and require resubmission.

Level 1 documentation is filed electronically on the SharePoint site in the Historical file for the appropriate DC.

Special warnings:

If during this level 1 process either the RNA support team or the DRA determines it warranted, a level 2 review can be initiated as directed in step 2.2.3 below.

2.2.2 Level 1 Review - All Remaining Customers

A level 1 review is required for every threshold incursion.

How to do:

DC management or designee will contact the customer upon attempted threshold incursion. At a minimum management/designee will inform the customer that a controlled substance was omitted because a threshold maximum was met, ascertain the reason for the threshold incursion, inquire as to any new business that the customer may be servicing and document the conversation. Based upon management's evaluation of the conversation the level 1 may be complete. If however management feels further evaluation is necessary, they may evaluate the customer's purchases relative to the past three month's purchases. The evaluation should include but not necessarily be limited to the following criteria:

- Review Customer Purchasing Profile if one has been completed; are sales consistent with their profile?
- Perform a web search on the customer to review possible business practices
- Contact the appropriate Sales representative to determine reasoning behind the sales.
- Contact the customer to inquire on sales volume, expected volume and nature of business.
- Previous sales were validated and approved.
- Sales have not increased more than 25% from any previous month.
- Sales are not increasing steadily.
- Sales are consistent with the customer type.
- Sales are consistent with any previous Sales or Customer communication.

NOTE: DC management/designee will document all conversations with customer utilizing the general communication form and/or SharePoint, retain all email pertaining to customer review and all other data utilized in the level 1 review. Documentation will be retained SharePoint as evidence of due diligence. Management will have reviewed the level 1 prior to filing in the Historical file in SharePoint.

It is imperative to document the following information regarding your Level 1 discussion with the customer:

- name of person called
- reasoning for attempted threshold incursion
- has customer taken on any new business recently? if so explain.
- all additional information discussed pertaining to level 1.

Failure to complete this area will result in rejection of Level 1 and require resubmission.

Result:

If the evaluation indicates that the customer's purchases are reasonable and that no further investigation is required, DC management will decide to:

- Continue to block item until the beginning of new month and sales history is refreshed. This will need to be communicated to the customer by either DC management or sales.
- Request a temporary/permanent threshold change by following step 1.3 above.

Special warnings:
If the evaluation is not conclusive:
- Escalate to the Level 2 Review

2.2.2.1 Level 1 Exception / No-Call List

At times, McKesson may make the business decision to adjust/set threshold levels of customers to an amount lower than the customers choosing. Those customers may be placed on a "No-Call" list and will be exempt from subsequent Level 1 contacts for the items that have been adjusted. Only a DRA will make the decision to grant such an exemption.

How to do:
1. Once a customer has been "capped" on a threshold of a base code, the DC may request the customer to be exempt from further Level 1 contact.
2. The DC will request the DRA to exempt.
3. If exemption is granted, the DC will create a Level 1 explaining the exemption, noting the exact circumstances, the date, the name of the DRA granting exemption, the date the exemption was granted and any other pertinent information surrounding the issue.
4. The DRA will add the name, DEA#, customer number and the date of exemption to the Do Not Call list on DRA sharepoint site.
5. The DC will utilize the Do Not Call list at their discretion found on the DRA regulatory sharepoint site.
6. DRA will provide updated information to Service First.
7. The DC will refer to initial Level 1 for any other attempted threshold excursion on future omit reporting.

If at any time the exemption is revoked, the customer will be removed from the Do Not Call list, and Level 1 notification and requirements will be addressed as in 2.2.2 above.

2.2.3 Level 2 Review

If the Level 1 Review as conducted by DC management / RNA support team is deemed inconclusive, or if regional director requires additional information, a Level 2 Review is required.

How to do:
If the Level 1 Review as conducted by DC management / RNA support team is deemed inconclusive, or if regional director requires additional information, a Level 2 Review is required.

1. Once a level 2 has been requested, a level 2 form (SharePoint Template found on the Regulatory SharePoint site) will be used to document the proceedings.
2. DC management will forward/communicate all Level 1 information to their DRA
3. DRA and DC management will discuss review process and conduct customer interview(s) if appropriate. (Refer to "Due Diligence" in section 4 below)
4. DRA along with DC management will determine if sales are appropriate and either;
   a. inform customer that sales of the item will be blocked until the beginning of the next month
   b. implement a temporary/permanent threshold change by following step 1.3 above

NOTE: RNA support team shall be substituted for DC management as required in the above steps. All conversations with customer will be documented. All parties will retain all email pertaining to customer review and all other data utilized in the level 2 review. Documentation will be retained in SharePoint as evidence of due diligence.

2.2.3.1 Subpoena

If a government / law enforcement entity issues the DC a subpoena for information pertaining to a current/active McKesson customer, the DC will constitute this as immediate grounds for a level 2 review.

How to do:

1. Once a subpoena has been received a level 2 will be initiated. The form (SharePoint Template found on the Regulatory SharePoint site) will be used to document the proceedings.
2. DC management will forward/communicate all Level 1 information to their DRA
3. DRA and DC management will discuss review process and conduct customer interview(s) if appropriate. (Refer to "Due Diligence" in section 4 below)
   - **NOTE -** In some instances the requesting authority will request confidentiality due to ongoing investigations and require you NOT to contact the customer or change any ordering until instructed otherwise. In that case, document as such with the Level 2 form. Perform additional due diligence without alerting the customer of the subpoena.
4. DRA along with DC management will determine if sales are appropriate and either;
   a. inform customer that sales of the item will be blocked until the beginning of the next month.
   b. implement a temporary/permanent threshold change by following step 1.3 above

NOTE: RNA support team shall be substituted for DC management as required in the above steps. All conversations with customer will be documented. All parties will retain all email pertaining to customer review and all other data utilized in the level 2 review. Documentation will be retained in SharePoint as evidence of due diligence.

2.2.4 Level 3 Review

If after the Level 1 and Level 2 reviews have been conducted and the transaction (s) are deemed "suspicious", a Level 3 review is necessary.

How to do:

1. Upon escalation to Level 3, **ALL** controls will be blocked.
2. The matter will be escalated to the SVP of Distribution Operations, Regional SVP, RNA VP (as needed) VPDO, VPGM and Regulatory Affairs.
3. The customer / transaction (s) are reported to DEA Headquarters as "suspicious". The local DEA office should be contacted to determine if the account is in good standing with the agency; this will be done by DC Management or Regulatory Affairs. Findings must be shared between DC Management and Regulatory Affairs.
4. Regulatory Affairs will schedule and conduct meetings with the Law Department and Senior Management to present the findings of the review process and discuss next steps.
5. With the Law Department's guidance, Regulatory Affairs or Counsel will contact the DEA Headquarters to discuss our findings.
6. The final review of customer purchases and decisions regarding their purchases will be determined by the Law Department and Senior Vice President.
7. Regulatory Affairs will notify the DEA Headquarters and Local Office of McKesson's findings and any decisions regarding continued business with the customer.
8. If there are outcomes to the review that impact the customer relationship with McKesson, Sales or Distribution Management will notify the customer.

2.2.4.1 Reinstatement

If after all proper due diligence has been performed and it has been determined that a "suspended" customer has met the requirements to once again distribute controlled substances, they may be reinstated. All reinstatements will be approved by the DRA, SVP of Operations and the Law Department. Notification of the customer reinstatement to the local DEA field office will be made at the direction of the DRA via mail/email using the following text:

"*Subsequent to prior correspondence and as part of our organization's ongoing diligence, McKesson conducted additional review of the below-referenced pharmacy in connection with our Controlled Substance Monitoring Program (CSMP). Based on these recent activities, we have resumed selling all controlled substances to this customer, effective as of (Date).*"

A copy of the correspondence will be retained in the customers CSMP file.

2.3 Threshold Removal

If at any time there is need to remove the customer's ability to purchase controlled substances, either completely or by base code, the DRA can make adjustments as detailed below.

How to do:

1. Block All Control Substance Purchases
   a. Sales Admin can remove the DEA number from customer master data or
   b. DRA can apply one of the following DEA families with the associated result

Family	When to Use
INEL	The customer number is **ineligible** to purchase controlled drugs but is an active customer number. This should be used when a customer number does not have a DEA number or has a DEA number but should not be buying the drugs (such as leads or OTC accounts). INEL will stop the ability to purchase even if a DEA number is on file.
TERM	The customer has **terminated** with McKesson and is inactive.
SUSP	The customer is **suspended** by Regulatory Affairs from purchasing controlled drugs. You should use this family when you're performing level 2 or 3 reviews and need to halt purchases. If a customer in this situation eventually leaves McKesson, I would leave the family as SUSP for future reference.

2. Block Specific Base Codes
   a. The DRA can enter "0" into threshold amount for specific base code (s)

Section Top

3. New Customer On Boarding Process

It is extremely important as part of McKesson's ongoing commitment to Controlled Substance Monitoring and understanding our customers business practices that Sales and Operations work collaboratively to inform, investigate and authorize all new customers controlled substance purchases.

Special warnings:
Failure to complete all required forms or information will prevent or limit sales of controlled substances to customer.

3.1 Introducing new McKesson customers to Controlled Substance Monitoring (CSM)

How to do:
During the customer on-boarding process, the McKesson sales representative will introduce the CSMP. The sales rep will utilize the CSMP communication letter, CSMP Overview and CSMP FAQ (see attached) to inform customer of McKesson's responsibility and customers requirements.

Special warnings:
NOTE: At no time is there a guarantee, implied or otherwise, that any customer will be able to purchase controlled substances based upon information received during this process.

3.2 Customers Questionnaire

How to do:
Upon explanation/ presentation of McKesson's CSMP process, the sales rep will present, explain and request signatures for the specific customer questionnaire per business segment as detailed in the steps below. (see also attachments).

Special warnings:
NOTE: All customer questionnaires must be completed **legibly and completely.**
All questionnaires must be attached to the template on the Regulatory SharePoint site after completing the document per the above instructions. Forward all questions to your Director of Regulatory Affairs for your region.

3.2.1 RNA / Chain Customer Questionnaire

Because RNA, chain pharmacy customer's typically have their own regulatory departments and oversight, the abbreviated customer questionnaire form can be utilized. It may be completed by the customers home office or controlling branch on behalf of all of their operating units and/or stores.

3.2.1.1 Header Portion

If customer questionnaire is being completed on behalf of multiple locations, attach/submit electronically the detailed information (as noted below) for each location.

How to do:
Indicate whether new account is a new customer or existing customer.

New customer = New account not currently serviced by McKesson
Number of Pharmacies = number of locations to be serviced
Go Live Date = anticipated start date

Existing customer = Account currently serviced by McKesson, opening additional location(s) and/or secondary/warehouse account that is becoming primary with McKesson.

Indicate the number of locations/stores being activated and estimated "go-live" date.

3.2.1.2 1 General Information & Licensing

How to do:

a. Corporate Name / DBA if differs from corporate name (attach listing if multiple sites)
b. Store Number (attach listing if multiple sites)
c. Pharmacy Address (attach listing if multiple sites)
d. Phone/Fax (attach listing if multiple sites)
e. Pharmacy License - State / License # (Include all states in which licensed)
f. DEA registration number (list number on form. Attach listing if multiple sites)

3.2.1.3 2 Purchasing Information

In order to understand the new customers current controlled substance purchase requirements it is necessary to obtain past controlled substance purchasing information. File/data should be if at all possible, be provided electronically.

How to do:

a. Total estimated monthly purchases $
b. Total estimated monthly Rx purchases (including c.s.) $
c. Purchase breakdown:
   - Rx % (including listed chemicals and controlled substance)
   - Controlled Substance %
   - Listed chemical %
   - Non-Rx (OTC/HBA/DME) %

3.2.1.4 3 Controlled Substance Purchases

How to do:

Attach a file indicating:

a. Pharmacies with highest Dose units (tablets/capsules) dispensed per month for each of the following Controlled Substances. Total of all brand and generic for the base items, including combination products.
   - Hydrocodone
   - Phentermine
   - Oxycodone
   - Methadone
   - Alprazolam
b. Provide information for 90 Days' appropriate data (less than 90 Days if approved by DRA) to support purchase levels.
c. DRA to highlight which locations, with purchases in these areas, require additional follow-up, on the following pages.

3.2.1.5 4 Ownership/Business History

Complete sections as indicated. Utilize the explanation box to explain and/or include any other relevant information

How to do:

a. Ownership type (indicate by check mark the business type)
b. Number of years in operation

3.2.1.6 5 Business Information

Complete sections as indicated. Utilize the explanation box to explain and/or include any other relevant information

How to do:

a. List wholesale distributors used in the last 24 months
b. How do the highlighted pharmacies in Section 3, receive business, please list percent %.
c. Are the above pharmacies affiliated with an Internet Website or have their own site? If yes, please provide web addresses:
d. Do these pharmacies download and fill prescriptions from a website? If yes, please provide web addresses:
e. Pain management clinics
    i. Do these pharmacies provide direct service to or receive significant business from Pain Management Clinics?
    ii. List
f. Do any of these pharmacies service nursing homes, long term care or hospice facilities?
g. Are any of these pharmacies located in a medical center or clinic?
h. Do any of these pharmacies operate any closed door pharmacies?
i. Do any of these pharmacies regularly fill prescriptions written by out of state providers?

3.2.1.7 6 Regulatory Control

How to do:

a. Does chain have a dedicated Regulatory Control/Compliance resource that is responsible for monitoring pharmacy purchases of controlled substance?
    - Yes -If Yes, Name/Contact Info
    - No
b. Does chain pharmacy management regularly review pharmacy purchases of controlled substances?
    - Yes No
c. Please describe below the process and tools used to monitor CS purchases made by individual pharmacies. Explanation:

3.2.1.8 7 Review of McKesson Controlled Substance Monitoring Program (CSMP)

Review the overall CSMP program. You should utilize the FAQ's and overview found in the attachment section below.

3.2.1.9 Signatures

McKesson and customer Representative will print, sign and date the form attesting that all the information within is accurate.

3.2.2 Independent/Small/Medium Chain (ISMC) Questionnaire

A completed customer questionnaire is mandatory for every new McKesson customer prior to them receiving controlled substances. The regulatory department must approve new customer(s) based upon questionnaire information/supporting documentation prior to threshold setting.
The customer is not allowed to complete the questionnaire themselves, the questionnaire is meant to document interactive communications between McKesson and the customer. The questionnaire will be completed by the McKesson sales representative.

Special warnings:
Customer will not be allowed control substance purchases without regulatory approval based upon completion of customer questionnaire and supporting documentation.

3.2.2.1 Header Portion

If customer questionnaire is being completed on behalf of multiple locations, attach/submit electronically the detailed information (as noted below) for each location.

How to do:
Indicate whether new account is a new customer or existing customer.

New customer = New account not currently serviced by McKesson
Existing customer = Account currently serviced by McKesson, opening additional location(s) and/or secondary/warehouse account that is becoming primary with McKesson.

Indicate the estimated "go-live" date.

3.2.2.2 I General Information & Licensing

How to do:
a. Pharmacy Name (enter pharmacy / customer name as it appears on DEA registration)
b. Pharmacy Address (enter information as it appears on DEA registration)
c. Phone/Fax
d. Pharmacy Email address (if applicable)
e. Pharmacy License (include all states in which licensed)
f. DEA registration number (list number on form)
g. Pharmacist License (list all pharmacists' licenses, the state and license number. Indicate the Pharmacist in Charge (PIC).)

3.2.2.3 II Ownership/Business History

Complete sections as indicated. Utilize the explanation box to explain and/or include any other relevant information

How to do:
a. Owner information
b. Ownership type (indicate by check mark the business type)
c. Number of years in operation
d. Owner operates/affiliated with additional pharmacies? (if so, list)
e. History
f. Criminal background checks

3.2.2.4 III Business Information

Complete sections as indicated. Utilize the explanation box to explain and/or include any other relevant information

How to do:

a. Business Type (circle the type of business this customer represents)
b. List wholesale distributors used in the last 24 months
c. How does pharmacy receive business. List estimated %.
d. Is the pharmacy affiliated with an internet website or has its own site? (list address)
e. Does pharmacy download / fill prescriptions from a website?
f. Pain management clinics (Indicate the % of the customers overall business which is attributed to pain management business. Detail any pain management clinics that customer may be doing business with. Include a listing of individual customer(s) and their associated pain clinic (s).)
g. Does pharmacy service nursing homes, long term care or hospice facilities?
h. Is pharmacy located in a medical center or clinic?
i. Is this a closed door pharmacy?
j. Does pharmacy regularly fill prescriptions written by out of state providers?
k. What are the areas of specialty of the doctors' practices for which the pharmacy dispenses controls?

3.2.2.5 IV Top (5-10) Controlled Substance Prescribers

How to do:

List names and DEA information of the top controlled substance prescribers.

3.2.2.6 V Purchasing Information

In order to understand the new customers current controlled substance purchase requirements it is necessary to obtain past purchasing information.

How to do:

a. Total estimated monthly RX purchases including controlled substances.
b. Total Estimated Monthly Rx Purchases (including c.s.) $
c. Purchase breakdown (approximate)
d. Prescriptions filled per day/month

3.2.2.7 VI Controlled Substances Purchases

McKesson requires specific usage information for lifestyle type substances (Hydrocodone, Oxycodone, Alprazolam, Phentermine, Methadone) in order to assess the customers' current requirements.

How to do:

a. Estimate dose units dispensed per month for each of the following controlled substances, hydrocodone, oxycodone, alprazolam, phentermine and methadone. This information should contain the total for all brand and generic for the base ingredient including combination products
   - 1 tab, cap = 1 dose
   - 1 ounce = 1 dose
   - 1 ampul/vial/injection = 1 dose
b. If any of the above is greater than 5000 dose units, please provide information to support purchase levels. (Supporting information will include 6 months of dispensing data (less if approved by DRA), referrals

from pain clinics, etc)

c. Has the pharmacy established policies and procedures to verify controlled substances prescriptions? If so how?

3.2.2.8 Customer Signature and Attestation

Upon completion of the customer questionnaire, the owner and/or PIC will sign/date and attest to the documents accuracy and completion.

3.2.2.9 Physical Inspection

An important part of the on boarding process and fulfillment of our obligation to "know our customer" is the site visit/observation process. First impressions are important and should be noted, however utilizing the questionnaire is a more formal way to memorialize the observation information.

How to do:

a. General description of pharmacy and surrounding area in which the business is located, include the condition of the pharmacy.
b. General description of the pharmacy customers.

The information listed here will assist in the site visit/observation.

Observations should include items such as the following:¨

- Customer Traffic - does the customer volume seem in line with their business type?
- Signage - does the customer advertise themselves to the public in a manner consistent with their business type?
- Location - is the customer's business in a site that appears consistent with their business type and volume? For example, consider the area's population and surrounding businesses.
- Store Size - does the customer's square footage appear to be appropriate for their business type and volume?

c. Does the pharmacy have adequate security?

Photograph pharmacy outside and inside, including front entrance, pharmacy interior and pharmacy counter.

3.2.3 Customer Interview

How to do:

Instructions for performing the interview

1. Notify the appropriate Sales team member that an interview must be conducted with the customer.
2. Sales or Operations should contact the customer and request a meeting at a mutually agreed upon date and time. NOTE: All meetings should be conducted on the dispensing pharmacy premises in order to view the pharmacy operations.
    - Schedule the meeting for as soon as is possible for all parties; the DEA expects McKesson's responses to suspicious activities to be prompt and timely.
    - Ensure that the customer understands that McKesson is performing due diligence activities for the benefit of both McKesson and the customer.
3. Print and review the customer questionnaire prior to visiting the customer.
4. Conduct the interview.
5. Have the customer sign the questionnaire.
6. Thank the customer and exit the interview

7. Complete and sign the customer questionnaire based upon responses provided by the customer.

3.2.4 National Institutional Pharmacy Questionnaire (MHS, Government accounts, etc)

Because National Institutional pharmacy customer's typically have their own regulatory departments and oversight, the abbreviated customer questionnaire form can be utilized. It may be completed by the customers home office or controlling branch on behalf of all of their operating units and/or facilities.

3.2.4.1 Header Portion

How to do:
Indicate whether customer is new or existing and the "go live" date. Also complete customer name.

3.2.4.2 I General Information & Licensing

How to do:
Please attach file listing the following
a. Corporate Name:
b. Pharmacy License: Attach listing of Pharmacies & Licenses
c. DEA License: Attach listing of Pharmacies & Licenses
d. Has any pharmacy location had pharmacy license or DEA license suspended: Yes No - If yes, explanation on addendum.

3.2.4.3 II Business Information

How to do:
a. Check box adjacent patient base serviced by pharmacies:
- Pain Management Clinics*Hospice
- Long Term CareAcute care hospital
- Surgery CentersSatellite Clinics
- *Name/address of Pain Management Clinics serviced on addendum.

b. Do pharmacies fill prescriptions from Internet Website? Yes No If yes, provide web address in addendum.

3.2.4.4 IV Purchasing History(New Customer Only)

How to do:
a. Total Monthly Purchases by Pharmacy
b. Controlled Substance Purchases by Pharmacy
   - Attach file/listing of purchase history for controlled substances segregated by pharmacy, by item (NDC)

3.2.4.5 III Regulatory Control

How to do:

a. Is there a dedicated resource responsible for Regulatory Control/Compliance? Yes No Contact Information
b. Are the processes/systems in place to regularly review pharmacy purchases of controlled substances? Yes No

3.2.4.6 V Review of McKesson Controlled Substance Monitoring Program (CSMP)

Review the overall CSMP program. You should utilize the FAQ's and overview found in the attachment section below.

3.2.5 Clinical Customer Questionnaire

McKesson Pharma customers that fall into the category of a "clinic" require a questionnaire specific to them.

A clinic will be defined as a medical establishment, generally outpatient, run by several doctors sharing the same facilities. The owner of the drugs is the DEA license holder. State requirements and license types may vary from state to state, but all must have a valid DEA license to order controlled substances.

Typically, clinics will not write and fill prescriptions for controlled substances in their establishment. If that is the case, only part 1 of the clinic questionnaire will need to be completed.

However, if they do write and fill prescriptions from their office or resell products to other medical providers, the customer will be required to complete questionnaire parts 1 and 2.

See attachments section for both part 1 and 2 of the clinical questionnaires.

3.3 340B Covered Entity/Contracting Pharmacy Accounts

340b is a section of the Veterans Health Care Act 1992 that allows for the limiting of cost of pharmaceuticals to certain federal purchasers. It then allows access to reduced cost of drugs sold to certain health care facilities known as "Covered Entities".

This section deals directly with the sale of controlled substances to a 340b account.

Definitions as they relate to this section are:

- **Covered Entity:** The responsible party that will order the drugs and is responsible for the invoices (Bill To)
- **Contracting Pharmacy:** The entity that receives the drugs (Ship to)
- **McKesson Customer:** Retail (Independent or National) and MHS customers that McKesson holds the primary wholesaler relationship
- **222 Form/Blank:** Form that is filled out and submitted by the Contracting Pharmacy (ship to) which details the item description and quantities being ordered by the covered entity. The form must be delivered to the DC within 3 days of the order being placed. It must be delivered by a ***McKesson*** delivery driver, mailed or brought to the DC by the Pharmacy. This form is only used for the Class II drugs (CII's)
- **3rd Party Vendor:** A software vendor that facilitates the ordering process with McKesson, Covered Entity and Contracting Pharmacy. They often will place the orders on behalf of the Covered Entity and submit electronic notification to the Contracting Pharmacy to submit the

222 Form/Blank to the servicing DC.

In setting up accounts that are comprised of McKesson MHS and Retail and Non-McKesson MHS and Retail entities in both the bill to and ship to positions, it is important to know

- which accounts we will allow to order/ship controlled substances
- that the "bill to" differs from the "ship to" on these accounts
- and it is the "ship to" (Contracting Pharmacy) that has the DEA and Pharmacy Licenses info loaded. The DEA requires the ship to be accountable for the dispensing regulations/reporting on these specific drug types.

Special warnings:

Control drug threshold limits are not increased/decreased with the addition of these accounts on our current Retail National/Independent customers

3.3.1 Controls "Ship To" Decision Matrix

How to do:

Which Accounts will we allow the shipment of controls?

Covered Entity McK Customer?	Contracting Pharmacy McK Customer?	Will we allow the ordering/delivery of C2's?
Yes	Yes	Yes
No	Yes	Yes
No	**No**	**No**
Yes	**No**	**No**

Special warnings:

***Any set ups outside of this decision making matrix will need to be approved by VPGM, Director of Regulatory Affairs and HSNA 340B Manager. We will only allow the ordering/shipping of C2's to McKesson retail customers. Walgreens will be the only exception due to their current 340B Contracting Pharmacy relationship with McKesson. (please note definition of McKesson Customer)

3.3.2 Loading of the Account- Roles and Responsibilities

Please note that even if an account has the DEA Registration and controlled substance schedule eligibility loaded in DCUS, it does not mean that they will be able to receive the controlled substances until the family classification has been assigned by the DRA.

How to do:

Role/Position	Responsibility
Sales Administrator	Loads DEA Registration Number and schedule eligibility.
Sales Administrator or Field Account Manager	Submits SharePoint form to load controlled substance ordering ability to their account via CSMP family request
Distribution Center Manager	Reviews and approves request
Director of Regulatory Affairs	Requests CSMP customer family load by Master Data

HSNA 340B Manager	3rd Party Vendor Liason/Oversees process

3.3.3 Ordering Process

How to do:
Covered Entity places the order or 3rd party vendor places the order on behalf of the customer.

Process	Process Detail	Exceptions/Additional Info
Ordering	Order is placed by **Covered Entity** or **3rd Party Vendor** on behalf of Covered Entity	Account number for the bill to/ship to relationship must be submitted to the pharmacy for proper documentation on the 222.
3rd Party Vendor	If the 3rd party vendor is ordering on behalf of the Covered Entity then they must provide notification to the Contracting Pharmacy to Submit the 222/Blank	
222/Blank Form	**Pharmacy** must fill out the 222/Blank and submit to the DC. The bill to/ship to account number must be written in the upper right hand corner of the 222 form	The form must be delivered to the DC within 3 days of the order being placed. It must be delivered by a ***McKesson/Courier*** delivery driver, mailed or brought to the DC by the Pharmacy. This form is only needed for the Class II drugs (CII's).
Distribution Center	Match 222/Blank with incoming orders placed, fill order and deliver to Contracting Pharmacy	**There are never to be any substitutions as far as items ordered on these accounts.** The customer number will be on the upper right hand corner of the 222/Blank on the 340B Bill To/Ship To accounts. In the event they are not, you will need to match the DEA to the order qty/info from your incoming orders.

Section Top

4. Due Diligence

McKesson's responsibility is to "Know Our Customer". If at any time McKesson (this includes sales, operations, regulatory) suspects inappropriate activity and/or questionable practices, McKesson has the responsibility to act. This requirement is regardless of customer type, size, tenure, revenue, purchase quantities or threshold amounts.

Regulatory and/or DC management may request a customer site visit, observation and/or signed questionnaire at any time. Regulatory may also suspend shipments of controlled substances at any time.

How to do:
Due diligence may include any or all of the following activities:
- Customer Declaration
- Customer's Self-Certification
- Site visit / observation

- Follow up interview
- Inquiries with local DEA, Board of Pharmacy
- Web search
- Requesting extensive background search via corporate security
- Photographs

1. Customer Communications
   - All communications regarding controlled substances are subject to subpoena and discovery.
   - Include in the subject line of emails, customer name and/or acct#
   - Write information as if it were being viewed by the DEA
   - Be complete and detailed…remember utilize the 5 W's
     - Who, what, when, where and why
   - Refrain from using the word "suspicious" in communications.
     - Once McKesson deems an order and/or customer suspicious, McKesson is required to act. This means all controlled substances sales to that customer must cease and the DEA must be notified.
   - Document ALL conversations where controlled substances are concerned or discussed. (use the standardized form in the attachments section)
   - Phone, intrapersonal conversations with customers should be documented and retained at the DC.

2. Legal Communications
   - Communications copied to McKesson's legal department must contain the following text:
   - **Privileged and Confidential**
   - This may be included in the subject line and/or the body of the text.
   - Doing so protects information as attorney client privilege.

Special warnings:

Any activity taken with regards to CSMP should be properly documented and retained. Emails, contracts, government contact forms, notes from phone conversations, photos etc may be collected as evidence and as such should be legible, detailed and accurate.

4.1 Director of Regulatory Site Visits

As part of continued due diligence, the DRA's will on occasion conduct their own site visits to customers within their region and/or other regions as requested.

How to do:

DRA's will conduct site visits on those customers as needed/warranted. They will use the **Site Visit Template** as found in the attachments below. The completed form will be retained in the DRA's SharePoint site for future reference.

Section Top

5. Document Retention

It is imperative that documentation regarding CSMP is retained in an easily accessible/retrievable manner. This documentation can be requested by the DEA, State authority and McKesson Regulatory/Law department to support an investigation, audit or inquiry.

How to do:

All documentation related to CSMP will be maintained in a central location and retained for a period of eight (8) years.

Records include, but not exclusively: customer questionnaires and other Due Diligence documentation to determine eligibility for dispensing controlled substances and supporting documentation (e.g., emails, Level 1 documents, threshold change requests, customer dispensing data, and photos of establishment).

A. Distribution Centers

- SharePoint can/will be utilized for all electronic/scanned documentation
- When SharePoint is not available and/or the type/size of file is not conducive to storing on SharePoint, a hard copy will need to be retained as in the steps below.
- **All DC's are required to maintain a 4 drawer file cabinet (minimum) that is for the sole and exclusive use of CSMP documentation. It will be marked as CSMP.**
- Emails and electronic copies are to be kept in the same manner in the CSMP file.
- Government contact forms are to be disseminated as per distribution list on form.

B. RNA/National Institutional Accounts

- RNA and national Institutional offices will also maintain a dedicated file (s) whose sole purpose is to maintain CSMP documentation, questionnaires etc.
- Emails and electronic copies are to be kept in the same manner in the CSMP file

GUIDING PRINCIPLE: Any CSMP document should be able to be retrieved within 30 minutes of request.

Special warnings:

Requests for information/documentation by DEA or other Authority must be accompanied by a written request and approved by McKesson Legal department prior to release of information.

6. DEA Reporting Requirements

As per the McKesson/DEA agreement, McKesson will provide the following information to the DEA:

- On a daily basis, McKesson will report any controlled substance transactions/customer that is deemed "suspicious". This process will be performed centrally by the Directors of Regulatory Affairs.
- On a monthly basis, McKesson will provide reports of all non-reportable controlled substance transactions.

6.1 Suspicious Order / Customer Reporting

If at any time a customer or customer transaction is discovered and deemed to be "suspicious", that customer shall be reported to the appropriate Director of Regulatory Affairs. The Regulatory Affairs department will notify the appropriate DEA offices and provide to them any required information. Distribution centers will be directed to contact their local DEA field offices to report the suspicious customer/transaction as needed by their regional DRA.

Suspicious orders/transactions/customers can be discovered by way of the Level 1, 2, 3 process, DC partner input and/or sales interaction.

6.2 Monthly Transaction Reporting

In addition to the monthly ARCOS reporting of reportable controlled substances, McKesson will also report all non reportable controlled substance transactions. To be able to produce these reports, all controlled substance transactions will be sent to central BI reporting systems three business days after the order has been invoiced. This process will be automatic. In order to properly accumulate the data, distribution centers will need to follow the steps below.

How to do:

1. All 222 narcotic blank numbers are required to be updated within three business days of the

transaction (sale, receipt, credit) so that the information is available for the reporting processes.
2. Ensure that the blank numbers are added before the data is sent from your distribution center.
3. An email will be generated to the DCM and DRA if narcotic blanks have not been updated at the end of the second and third business day.
4. At the end of day three the data will be transmitted regardless of whether you have completed your data entry.

Section Top

7. Auditing

On a monthly basis, all DC's will review and attest to the completion of certain required CSMP processes.

7.1 Threshold Change Form Review

1. Between the third and eighth workday of every new month, the DC will be provided a report of all adjustments made the previous month.
2. Distribution center will validate the existence of a TCR for every adjustment made
3. DCM or manager designee will sign, date and file the report in the CSMP file.

NOTE: there may be some occasions where a TCR was not utilized. In that event, documentation of DRA approval should exist to explain the adjustment.

7.2 Level 1 Documentation Review

Between the third and eighth work day of the new month, the DC will be provided a report that will identify items omitted during the previous month.

1. The DC will validate from the report that a level 1 has been conducted for each customer that was omitted due to CSMP thresholding.
2. DCM or designated manager will sign, date and retain in the CSMP file.

NOTE: Subsequent omits for the same product do not require additional Level 1 forms.

7.3 New Customer Questionnaire Review

TBD

Section Top

8. Continuing Education

In addition to all other continuing education efforts regarding regulatory compliance, the DC's and sales groups will receive an annual CSMP SOP overview and continuing education. The intent of this continuing education is to refresh/remind McKesson personnel of their CSMP responsibilities and instill consistency on CSMP processes.

How to do:

A. Yearly (within the first quarter of the fiscal year), a curriculum pertaining to the CSMP SOP will be made available to designated participants.
B. The training (s) will include DC management, DC(regional) sales team, DC designees that have CSMP responsibilities and RNA sales teams (as decided by the DRA's)
C. Those required to attend will receive notification via McKesson Center For Learning (MCL)
D. The training (s) will be self led instruction via the MCL portal.
E. After review, the user will virtually attest to completion.
F. Upon completion, the user will be required to answer a short list of questions to test for learning
   1. Attestation + successfully answering questions = completion.
G. The DRA's will be provided access to view participants completion/non completion reports.
H. DRA's will have access to completion reports via MCL platform as evidence of yearly training.
I. Topics of the CSMP SOP continuing education will include but are not limited to:
   1. On boarding
   2. Questionnaires
   3. Level 1 actions
   4. Threshold changes
   5. Due Diligence
   6. Monthly management review

Top

Attachments

Threshold Change Form
Click to Open or Save

RNA Threshold Change/Level 1 Form
Click to Open or Save

Retail Chain (RNA) Questionnaire
Click to Open or Save

ISMC Questionnaire
Click to Open or Save

National Institutional Pharmacy Questionnaire
Click to Open or Save

General Level 1, Observation, Communication Documentation Form
Click to Open or Save

Level 2 Form
Click to Open or Save

Family Matrix
Click to Open or Save

CSMP Customer Letter
Click to Open or Save

CSMP Overview
Click to Open or Save

Invoice Example
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CSMP FAQ
Click to Open or Save

Clinical Customer Questionnaire Part 1
Click to Open or Save

Clinical Customer Questionnaire Part 2
Click to Open or Save

Site Visit Template
Click to Open or Save

Top

Related Information

Pharma Procedure

MOM-CTRL-008
DEA Registration Procedure

MOM-REG-003
Customer DEA and State License Verification Procedure

Top

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Document Owner: Bruce Russell

Top

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05/27/2008
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05/27/2008

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Added ISMC Questionnaire

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Released to the Field

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added If an error occurs:
If the Vistex system is not available and/or the Director of Regulatory Affairs does not have access, the approval process for DEA Family uploading can be maintained via an email attachment whereby the Director gives approval.
to section 1.2

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07/25/2008
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revision to level 1 / RNA process

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approval to post received

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01/08/2009
Multiple changes - new RNA TCR, questionnaire, Institutional questionnaire

Revision #:
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01/30/2009
various updates including: new TCR forms/questionnaires for different customer types/level 2 form

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changed requirement for reporting list 1 chemical report in step 6.1

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Added DR46 requirement to step 6.2

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updated National Institutional Questionnaire

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updated the process to handle TCR, Level 1/2 and questionnaires to utilize sharepoint

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removed section on DU45 and DR46 reporting.

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verbiage change to section 4 Due Dilligence

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added a link to licensing SOP

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Added Customer's Self-Certification to second bullet Step 4

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Added revised ISMC questionnaire

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Added revised (updated signatures) CSMP customer letter

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added site visit template

Revision #:
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Added 2.2.4.1 reinstatement directions

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Added section 2.2.2.1 do not call list

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added step 2.2.3.1 to address Subpoena

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Added step 3.3
340B Covered Entity/Contracting Pharmacy Accounts which covers the handling of 340b accounts

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added revised families matrix

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Added level 1 requirements in step 2. Added continuing education step #8.

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added document retention to step #5

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1.34
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added updated ISMC questionnaire

Revision #:
1.35
03/19/2013
revised ISMC and RNA questionnaire sections to match verbiage in questionnaire attachments.

Revision #:
1.36
03/20/2013
updated the families matrix attachment

Revision Notes: The CSMP SOP revision of 1/30/09 is effective immediately, however the components are not auditable until February 16, 2009.
1.14 is effective immediately but not fully auditable until 10/29/09
1.15 is effective immediately
1.16 is effective immediately
1.23 is effective immediately but not fully auditable until 1/1/12
1.31 will be effective immediately upon implementation of MCL and Sharepoint changes
1.34 is effective immediately

No email? Send your comments to: **MOM Feedback**